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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,389	09/15/2008	Stefano Colloca	ITR0048YP	4904
210 MERCK P O BOX 2000 RAHWAY, NJ 07065-0907	7590 09/27/2011		EXAMINER PENG, BO	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 09/27/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,389	Applicant(s) COLLOCA ET AL.	
	Examiner BO PENG	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1, 6, 8, 43-46 and 48-50 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1, 6, 8, 43-46 and 48-50 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 24 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/24/06:6/16/09:4/5/10</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Restriction Election

1. Applicant's restriction election, without traverse, of Group I (Claims 1, 6, 8, 43-46 and 48-50), and species of SEQ ID NO: 1, in the reply filed on September 12, 2011, is acknowledged.
2. Claims 1, 6, 8, 43-46 and 48-50 are pending and are considered in this Office action.

Claim Objection

3. Claim 1 recites: "A replication-defective chimpanzee vector which is at least partially deleted in E1 and devoid of E1 activity-comprising the sequence of nucleotides as set forth in a) SEQ ID NO: 1." However, SEQ ID NO: 1 is the whole genome of ChAd3, which does not have a deletion at E1. To improve clarity, Claim 1 is suggested to be amended as:
A replication-defective chimpanzee vector derived from the genome of chimpanzee serotype 3 (ChAd3) of SEQ ID NO: 1, wherein the vector has at least partial deletion or disruption of E1 genes in SEQ ID NO: 1 and lacks E1 activity.
4. Claim 49 contains two ".,". Correction is required.

Claim Rejections - 35 USC 112, second paragraph

6. The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 6, 8, 43-46 and 48-50 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 43 recites: “A recombinant chimpanzee adenoviral (ChAd) vector which is at least partially deleted in E1 and devoid of E1 activity, wherein the adenoviral vector is derived from a ChAd3 chimpanzee adenovirus serotype” However, chimpanzee adenoviruses share great homology to each other and to human adenoviruses. The art of adenoviral vectors involves extended structural manipulations of different parts of different Ad viruses, such as chimeric Ad vectors from different Ad viruses. Thus, the description of the claimed Ad vector simply by referencing the source of adenovirus, such “the adenoviral vector is derived from a ChAd3” is not a sufficiently clear description of the claimed ChAd. One of ordinary skill in the art cannot be reasonably apprised of the metes and bounds of the invention because it is not clear what the structure of the referenced Ad vector is intended. This rejection affects all dependent claims. Claim 43 is suggested to be amended as “A recombinant chimpanzee adenoviral vector serotype 3, comprising the nucleotide sequence of ChAd3 genome which is at least partially deleted in E1 genes and devoid of E1 activity.”

9. Claim 50 is indefinite. First, Claim 50 contains the trademark/trade name PER.C6TM. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the

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goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to describe a host cell and, accordingly, the identification/description is indefinite.

Secondly, 293 and PER.C6 cells may be starting cells for making a cell comprising the recombinant adenoviral vector of Claim 43, but they are not the host cell comprising the recombinant adenoviral vector of Claim 43.

10. Appropriate corrections are required.

Claim Rejections - 35 USC 112

11. The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 6, 8, 43-46 and 48-50 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

13. The invention appears to employ novel biological materials, specifically novel chimpanzee adenovirus serotype 3 and ChAd3. Since ChAd3 and ChAd3 vector are recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. It is noted that Applicants have not deposited either ChAd3 or ChAd3 vector, and it is

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not apparent if the ChAd3 or ChAd3 vector is readily available to the public. The requirements of 35 USC 112 may be satisfied by a deposit of either the ChAd3 or ChAd3 vector and disclosure of a repeatable process to obtain the ChAd3 or ChAd3 vector in the specification.

14. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

15. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become unviable.

Applicants are directed to 37 CFR 1.807(b), which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

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- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicants is also directed to 37 CFR 1.809(d) which states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
 - (1) The accession number for the deposit;
 - (2) The date of the deposit;
 - (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
 - (4) The name and address of the depository.

16. Applicants' attention is directed to MPEP 2400 in general, and specifically to section 2411.05, as well as to 37 CFR 1.809(4), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information; however, Applicants is cautioned to avoid the entry of new matter into the specification by adding any other information.

Remarks

17. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648